



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 28 2000

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Robert P. Brady, Esq.
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109

Dear Mr. Brady:

This is in response to your letter dated February 10, 2000, to Dr. Susan Allen, Acting Director of FDA's Division of Reproductive and Urologic Drug Products, concerning safety issues associated with Viagra (sildenafil citrate). You ask that FDA require Pfizer, Inc. (Pfizer), the manufacturer of Viagra, to add a boxed warning to the Viagra labeling about the danger associated with concomitant use of Viagra and nitrate medications.

The issue of concomitant nitrate use was among those raised by Public Citizen in a citizen petition submitted on July 14, 1999, in Docket No. 98P-0561/CP1, and your letter has been filed in that docket as a comment. Today, we issued our response to that petition (see enclosure). In the response, we note that Pfizer revised the original approved package insert to strengthen the previous statement contraindicating the use of Viagra in patients taking nitrates (see pages 7-8). As noted in the response, we believe that these contraindications statements adequately advise against the use of Viagra in patients taking nitrates to control chest pain. Therefore, the Agency does not believe that a boxed warning is necessary at this time.

If you have further concerns about this issue, you may, of course, submit a citizen petition of your own in accordance with 21 CFR 10.30. Thank you for your interest in this matter.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

Enclosure

98P-0561

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